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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,700	01/14/2002	Colin Ratledge	401544	8613

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LEYDIG VOIT & MAYER, LTD
700 THIRTEENTH ST. NW
SUITE 300
WASHINGTON, DC 20005-3960

EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,700

Applicant(s)

RATLEDGE ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34,37-51 and 74-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,37-51 and 74-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The application should be reviewed for errors and conformity with domestic practice.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/04 has been entered.

Claims 34, 37-51 and 74-82 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 36-51, and 74, 78-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is incomplete in the absence of a recovery step for the product produced

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim 34 is vague and indefinite in that there is no clear indication as how the absence of "stationary phase" occurs.

Claim 37 is vague indefinite and confusing in lacking antecedent basis in claim 34 for "the use of a compound as a carbon source" that causes an increase in pH. It appears that "a compound" is intended to be acetic acid or acetate ion which is "the primary carbon source". There is no indication in claim 37 regarding "the increase in pH" that "control" will be responsive to or which is intended. The claim appears incomplete as written. It is recommended

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that the limitations of claim 38 be incorporated into claim 37.

In claim 40 it is uncertain what is intended by “controlling the addition to the medium”. The terms “the addition” lack antecedent basis in the claim. If acetic acid is intended to be added, this should be clearly set forth.

In claim 41 the trigger for the addition of other factors to the medium is uncertain. Is it random?

Claim 42 is vague and indefinite in that the antecedent basis for “said compound” is uncertain as noted for claim 37. The nature of the “further component” is unclear. Is it a further microorganism?

In claims 49-50 it is unclear what is intended by “initial”, since according to claim 47 there is a pre-culturing step with glucose.

Claim 82 lacks antecedent basis in claim 34 for “total extractable lipid”.

A proposed claim is presented below. Claims dependent on this claim would be allowable upon resolution of all 35 U.S.C § 112 issues. There would have been no motivation for one of ordinary skill in the art at the time the claimed invention was made to produce docosahexanoic acid by culturing a strain of *Crypthecodinium cohnii* wherein acetic acid or acetate are provided as the primary carbon source and wherein the process parameters are controlled in a manner that results in the absence of a stationary phase in the culturing process for the production of DHA.

34. (Currently Amended) A method for the production of docosahexanoic acid (DHA) with a strain of *Crypthecodinium cohnii*, comprising

- a) culturing the strain of *Crypthecodinium cohnii* in an aqueous nutrient medium containing a compound selected from the group consisting of acetic acid and an acetate ion; wherein the acetic acid or the acetate ion constitutes the primary carbon source for synthesizing DHA for the strain of *Crypthecodinium cohnii*; wherein the culturing process parameters are controlled in a manner that results in the absence of a stationary phase during the culturing process, and
- b) recovering the DHA produced.

No claim is allowed.

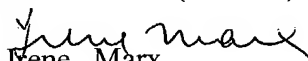
Any inquiry concerning this communication or earlier communications from the examiner

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should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
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